

## REMARKS

In the Office Action mailed November 29, 2005, claims 1, 3, 5-8 and 19-22 were examined. Claims 1, 3, 5-8, 19-20 and 22 are amended. Claims 1, 3, 5-8 and 19-22 remain in the Application.

In the Office Action mailed November 29, 2005, the Patent Office rejected claims 1, 3, 5-8 and 19-22 under 35 U.S.C. §112, second paragraph and 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

### A. 35 U.S.C. §112, Second Paragraph: Rejection of Claims 1, 3, 5-8 & 19-22

The Patent Office rejects claims 1, 3, 5-8 and 19-22 under 35 U.S.C. §112, second paragraph, as indefinite.

Independent claim 1 is amended to describe delivering GGTA1 knock-out swine cells. Support for the claim language may be found in the Application, for example, paragraphs 0086-0091.

Claim 3 describes the method of claim 1 wherein the donor cells are diploid and both chromosomal copies of a gene of a donor cell have been disrupted. Support for claim 3 may be found in the Application, for example, paragraph 0092.

Claim 5 describes the method of claim 1 wherein delivering comprises delivering an amount of donor cell to structurally reinforce the infarct region.

Independent claim 19 describes a method including applying a pacing therapy to a ventricle to pre-excite an infarct region to contract during systole at a time before contraction of the ventricle initiated by the His-Purkinje conduction network. Support for this amendment may be found in the Application at paragraph 0070.

Claim 22 depends from claim 19 and describes that the pacing therapy is based upon a sensed measurement. Applicants believe such claim is definite and no further description of a sensed measurement is required.

Applicants respectfully request that the Patent Office withdraw the rejection to claims 1, 3, 5-8 and 19-22 under 35 U.S.C. §112, second paragraph.

B. 35 U.S.C. §103(a): Rejection of Claims 1, 3 & 5-8

The Patent Office rejects claims 1, 3 and 5-8 under 35 U.S.C. §103(a) as obvious over "Influence of Embryonic Cardiomyocyte Transplantation on the Progression of Heart Failure in a Rat Model of Extensive Myocardial Infarction," Etzion, et al. (Etzion) in view of U.S. Patent No. 5,919,449 of Dinsmore (Dinsmore) and U.S. Patent No. 6,153,428 of Gustafsson, et al. (Gustafsson).

Etzion teaches the transplantation of rat embryonic cardiomyocyte into infarcted ventricles of rats.

Dinsmore teaches porcine or swine cardiomyocytes modified to be suitable for transplantation into a xenogeneic subject such as a human. The cardiomyocytes may be modified to express a gene product such as a growth factor or other factors that promote cardiomyocyte survival. See col. 5, line 64 through col. 6, line 31. The cardiomyocytes can be inserted into a delivery device which facilitates introduction by injection or implantation such as catheters. See col. 13, lines 54-59.

Gustafsson teaches transgenic swine in which the expression of  $\alpha(1,3)$  galactosyltransferase is prevented in an organ tissue type.

Independent claim 1 describes a method including identifying an infarct region within a ventricle of the human subject and percutaneously delivering GGTA1 knock-out swine cells that stimulate a beneficial response.

Independent claim 1 is not obvious over the cited references, because the cited references do not teach or provide any motivation for percutaneously delivering donor cells that stimulate a

beneficial response to an infarct region. The application references beneficial responses that include, but are not limited to, proliferation (paragraph [0030]) and expression of a beneficial polypeptide (e.g., growth factor or cytokine) (paragraph [0096]). The cited references, at best, describe cell therapies by delivering cells such as cardiomyocytes to a subject. None of the references describe delivering cells that stimulate a beneficial response such as by the human subject regenerating tissue in response to the introduction of donor cells.

Claims 3 and 5-8 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 3 and 5-8 are not obvious over the cited references.

**C. 35 U.S.C. §103(a): Rejection of Claims 19-22**

The Patent Office rejects claims 19-22 under 35 U.S.C. §103(a) as obvious over U.S. Patent Publication No. 2003/0105493 A1 by Salo ("Salo") in view of Etzion and further in view of Gustafsson.

Applicants respectfully request that the Patent Office withdraw the rejection under 35 U.S.C. §103(a) over the cited references because, at the time the application was filed, the application and Salo were owned by the same entity or subject to an obligation of assignment to the same entity and thus, Salo cannot preclude patentability under 35 U.S.C. §103(c).

**D. Double Patenting**

The Patent Office provisionally rejects claims 1, 5 and 7 under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 1, 2 and 4 co-pending U.S. Patent Application No. 10/414,602. With respect to claims 1 and 5 over claims 2 and 3 of co-pending U.S. Patent Application No. 10/414,767, Applicants respectfully request reconsideration of the double patenting rejection in view of the above amendments.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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Date: 4/12/06

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